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In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-640V Filed: October 11, 2017 Not to be Published.

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U.S. COURT OF

Tetanus-diphtheria-acellular pertussis ("Tdap") vaccine; tendinosis changed

to SIRVA; failure to file an expert report;

MARIO LEPORE,

Petitioner,

V.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Mario LePore, White Hall, MD, for petitioner (pro se). Claudia Barnes Gangi, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

dismissal

On July 22, 2014, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that tetanus-diphtheria-acellular pertussis ("Tdap") vaccine he received in his right arm on September 14, 2011 caused him tendinosis. Pet. at ¶ 6.

On July 24, 2014 and August 4, 2014, petitioner filed his medical records.

On August 20, 2014, petitioner filed a statement of completion of the record.

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

The undersigned held the first telephonic status conference on October 8, 2014, during which respondent requested medical records that preceded vaccination by three years as well as additional records. The undersigned set a deadline of November 24, 2014.

On November 24, 2014, petitioner moved for an extension of time until December 15, 2014 to file the additional medical records, which motion the undersigned granted.

On December 1, 2014, petitioner filed additional medical records.

On December 4, 2014, petitioner filed another statement of completion of the record. However, on January 5, 2015, petitioner filed an additional medical records.

On January 6, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel stated petitioner had an appointment with an immunologist at Johns Hopkins but he did not know when.

On February 5, 2015, respondent filed his Rule 4(c) Report, stating that prior to the vaccination, petitioner complained of left elbow pain for two weeks on August 23, 2011. Resp. Rep. at 2. About 1.3 years after Tdap vaccination, petitioner saw Dr. Koehler, an orthopedic surgeon, on December 5, 2012, for an evaluation of right shoulder pain. Id. Petitioner told Dr. Koehler that he had a persistent pattern over one year which was gradually increasing. He described his pain as moderate, dull, and aching. The pain was aggravated by work duties, overhead activity, and lifting. Med. recs. Ex. 4, at 3; Ex. 5. An MRI of petitioner's right shoulder on December 11, 2012 showed tendinosis and associated tendinitis. Med. recs. Ex. 4, at 2. Petitioner did not give a history that onset began less than 48 hours after the vaccination. Resp. Rep. at 8. Respondent recommended against compensation. Id.

On February 10, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel said petitioner's appointment with an immunologist at Johns Hopkins was in March 2015.

On April 1, 2015, petitioner filed the medical record of his visit to the immunologist at Johns Hopkins as exhibit 14. Dr. Eric T. Oliver saw petitioner on February 17, 2015 and took a history, during which petitioner said that he had no symptoms on the day of the Tdap vaccination, but a few days later, he developed aching and burning at the injection site (right shoulder), but no redness or swelling. This pain persisted for months. Then he noticed "atrophy" of his right deltoid and instability of his right shoulder. One year later, he developed bilateral knee pain and grinding of his right knee. He lost 25 pounds between 2011 and 2012 but his weight had returned to baseline. In recent years, he began experiencing similar symptoms in the opposite shoulder. Med. recs. Ex. 14, at 1. Dr. Oliver stated:

While fever and injection site induration are common adverse reactions, such symptoms are generally short-lived and would not explain the patient's current complaints. Based on his history, we have concluded that these symptoms are not due to an allergic reaction. ... [I]nflammatory markers were within the normal ranges. ... He does have significant shoulder pain and limited ROM, which could represent rotator cuff pathology. [emphasis in the original]

Id. at 5.

Also on April 1, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel said that Dr. Oliver referred petitioner to a rheumatologist whom he would see in mid-April.

On May 5, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel stated he did not have the rheumatologist's medical record. Petitioner's counsel also said he did not get responsive e-mails from petitioner. The undersigned ordered petitioner's counsel to file a status report by May 26, 2015.

On May 26, 2015, petitioner's counsel filed a status report saying that petitioner saw Dr. Jill Ratain at the Johns Hopkins Rheumatology Clinic on May 6, 2015. He had requested the records from this visit.

On June 3, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel said he had requested Dr. Ratain's records for the May 6, 2015 visit.

On July 7, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel said he had requested Dr. Ratain's records for the May 6, 2015 visit. Petitioner was seen at the Whitemarsh Clinic and petitioner's counsel had requested those records as well.

On August 6, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel said he did not have Dr. Ratain's records for the May 6, 2015 visit. He drafted a motion for a subpoena and would send it to the undersigned's law clerk.

On September 10, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel said the subpoena produced an invoice from Johns Hopkins which he would now pay. In an Order dated the same day, the undersigned gave petitioner a deadline of October 16, 2015 to file the medical records and scheduled another status conference for October 28, 2015.

On October 19, 2015, petitioner filed a status report stating counsel was still waiting for the medical records of petitioner's visit to Dr. Ratain.

On October 26, 2015, petitioner filed the medical records of his visit to Dr. Ratain on

May 6, 2015 as exhibit 15. The visit is dated April 16, 2015, not May 6, 2015. Med. recs. Ex. 15, at 1. Dr. Ratain, a rheumatologist, took a history from petitioner that he received Tdap vaccine in September 2011 in his right deltoid and, a couple of weeks later, his right should burned and ached. He said he lost 20 pounds and had atrophy at the vaccine site. He saw an orthopedist and underwent an MRI of the right should which showed some tendinitis, but no other abnormality. Now he had the same symptoms in his left shoulder and under his shoulder blades. Id. After performing a physical examination and doing blood tests, Dr. Ratain's opinion was that petitioner had impingement syndrome in both shoulders, but he did not have either autoimmune disease or inflammatory arthritis. Id. at 3. She suggested he see an orthopedist. Id.

On October 28, 2015, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel said he had no game plan and would speak to petitioner. The undersigned issued an Order dated the same date, giving petitioner's counsel a deadline of November 30, 2015 to speak to petitioner, and scheduling another status conference for December 7, 2015.

On November 27, 2015, petitioner's counsel filed a motion to withdraw. The undersigned held a telephonic status conference with counsel, during which petitioner's counsel said petitioner had not told him that he found a new attorney, and petitioner's counsel sent petitioner's file back to him.

On January 13, 2016, the undersigned issued an Order granting petitioner's counsel's motion to withdraw and petitioner became pro se.

On March 15, 2016, the undersigned held the first telephonic status conference with petitioner pro se and respondent's counsel. Petitioner said he is an audiovisual technician. Petitioner said he wanted to amend his petitioner to allege SIRVA. The undersigned gave petitioner a deadline of April 14, 2016 to file his amended petition.

Petitioner did not file an amended petition by April 14, 2016.

On April 25, 2016, the undersigned held a status conference with petitioner who stated he was still working on his amended petition and still trying to find an attorney. He had tried one or two attorneys. He said the biggest confusion was the allegation that he had a reaction to the vaccine. He said nothing other than the vaccination could be the cause. He had the vaccination in his right arm and his problems are in his right arm. He saw his personal care physician Dr. Madder about his shoulder issue. Dr. Madder wanted to refer petitioner to a specialist. Petitioner fixes audio and video systems. In an Order dated April 26, 2016, the undersigned left open the deadline for petitioner to file an amended petition.

On June 22, 2016, the undersigned held a status conference with petitioner who said he was no longer looking for an attorney to represent him and that he had not been looking for a medical expert because petitioner thought he has SIRVA. Respondent's counsel said his client HHS did not accept that petitioner has SIRVA. No medical record supported that petitioner had

SIRVA. The undersigned read to petitioner and respondent's counsel excerpts from petitioner's treating neurologist, Dr. Allan Genut who, on February 12, 2013, stated he was unable to find any neurological abnormality to explain petitioner's symptoms and that the burning sensation radiating down to his hand did not suggest a shoulder pathology. Med. recs. Ex. 6, at 4. The undersigned also read from the notes of Dr. Umasuthan Srikumaran who, on April 4, 2013, stated on physical examination that petitioner had no evidence of atrophy anywhere around the shoulder girdle and had full strength and range of motion. Med. recs. Ex. 7, at 2. Dr. Srikumaran's impression was that petitioner had a partial tear of his rotator cuff, tendinitis, and biceps tenosynovitis. Id. Dr. Srikumaran noted that petitioner did not have signs of suprascapular neuropathy. Id. Petitioner said he would file an amended petition and the undersigned set a deadline of September 22, 2016, and scheduled a status conference for October 24, 2016.

By informal communication with the undersigned's law clerk, petitioner moved for an extension of time until November 28, 2016 to file his amended petition, which the undersigned granted and cancelled the October 24, 2016 status conference. The new deadline was seven months after the original deadline of April 14, 2016. In an Order dated October 3, 2016, the undersigned reminded petitioner that the undersigned could dismiss his case if he did not prosecute the case or did not follow a court order. The undersigned noted that petitioner had failed to comply with several of the undersigned's orders. Petitioner had also failed to do any substantial work on his case. The undersigned concluded the Order of October 3, 2016 with the sentence: "Therefore, if petitioner fails to file an amended petition by November 28, 2016, the undersigned will dismiss this case. . . ."

Petitioner sent an e-mail to the undersigned's law clerk protesting the Order of October 3, 2016 and asking for a suspension of the case. In response to petitioner's e-mail, the undersigned issued an Order dated October 7, 2016 giving petitioner six months to file an expert report supporting his allegations by April 6, 2017. If petitioner failed to file an expert report by that date, the undersigned stated she would dismiss petitioner's case.

On March 15, 2017, petitioner filed a First Amended Petition for Vaccine Compensation, alleging that the Tdap caused him the Table Injury shoulder injury related to vaccine administration ("SIRVA"), together with exhibits 16-21. Petitioner alleges that he had the Table injury SIRVA. In paragraphs 3-4, petitioner recites symptoms that are not reflected in his first medical visit to an orthopedist about 15 months later. Interestingly, in petitioner's exhibit 17, at 5, Dr. Tae Hwan Chung diagnoses petitioner with tenderness of right deltoid and upper part of biceps, with rotator cuff tendinopathy and biceps tendinitis. Otherwise, petitioner's neuromuscular examination was unremarkable. Exhibit 19, at 1, has the results of an EMG and nerve conduction study which were negative. An MRI of petitioner's right shoulder showed mild atrophy and fatty infiltration of the right deltoid muscle with suggested mild fasciitis, and a partially evaluated rotator cuff with tendinopathy and possible low-grade tears. Med. recs. Ex. 20, at 15. Dr. Chung on January 12, 2017, believing petitioner's newly created history that he had pain after Tdap vaccination in 2011, opined that petitioner might have macrophagic myofasciitis due to poor digestion of vaccine-related aluminum compound by macrophages.

Med. recs. Ex. 21, at 14.

The new Table regulations list and define the Table injuries in 42 C.F.R. § 100.3(a) (Vaccine Injury Table) and (b) Qualifications and Aids to Interpretation ("QAI"). In 42 C.F.R. § 100.3(a), SIRVA is a Table injury for tetanus and other vaccines if the onset occurs up to 48 hours post-vaccination. In 42 C.F.R. § 100.3(b)(1), the QAI for SIRVA states:

SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction.

SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.) SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy.

On May 8, 2017, the undersigned issued an Order stating that petitioner continually asserts he does not need an expert to opine on his case because he is asserting SIRVA. The undersigned cited 42 U.S.C. § 300aa-13(a)(1) which prohibits the undersigned from ruling for a petitioner based solely on his allegations unsubstantiated by medical records or medical opinion. The undersigned said that none of petitioner's medical records support his allegation that he has SIRVA. Moreover, respondent denies petitioner has SIRVA. Petitioner had not filed an opinion from an expert saying he has SIRVA. The undersigned ordered petitioner to show cause by June 16, 2017 why the case should not be dismissed.

On June 12, 2017, petitioner e-mailed a response to the undersigned's Order to Show Cause which the undersigned filed by the undersigned's leave on the same date. Petitioner states that his recent medical records (exhibits 16-21) prove that he has SIRVA. He goes through the definition of SIRVA in the Vaccine Injury Table and says he fits within it. Moreover, he states he does not fall within any of the exceptions to the definition of SIRVA.

On July 28, 2017, respondent filed his Amended Rule 4(c) Report and Reply to Show Cause Response. Respondent notes that petitioner gave an onset history to his treating doctors in exhibits 16-21 which differs from the history he gave to his treating doctors in earlier medical records; petitioner said he had achiness at the injection site one day after the vaccination on September 14, 2011, which progressed over the next six months to become excruciating pain. Resp. Am. Rep. at 2. Respondent notes again that petitioner did not seek treatment for pain until about 1.3 years following the vaccination. <u>Id.</u> at 4. Petitioner repeatedly stated in his earlier medical histories that onset of pain was gradual, which is inconsistent with the more recent history petitioner gave that he had severe onset of pain at or near the vaccine site within 48 hours of the vaccination (an onset required for SIRVA). <u>Id.</u>

On August 1, 2017, the undersigned issued an Order setting a new deadline of September 29, 2017 for petitioner to file an expert report from a doctor stating petitioner has a vaccine injury and stating the basis for the expert's opinion.

On August 4, 2017, the undersigned issued an Order granting petitioner's informal motion through e-mail to the undersigned's law clerk to respond to respondent's amended Rule 4(c) Report and response to the undersigned's Order to Show Cause. The deadline for petitioner's response was September 5, 2017.

On August 7, 2017, the undersigned issued an Order due to petitioner's e-mailing the undersigned's law clerk with several questions about the case. To avoid any ex parte communications, the undersigned answered petitioner's questions in the Order. Petitioner asked why his medical records from Dr. Chung (exhibits 17, 18, 21) and the most recent MRI (exhibit 20) are not considered expert medical records which would satisfy the undersigned's August 1, 2017 Order to petitioner to file an expert report. The undersigned answered that there is a discrepancy between petitioner's earlier histories to doctors and his more recent histories which calls into question the bases of the recent Dr. Chung's opinions of his illness and its cause since Dr. Chung did not have petitioner's earlier medical records upon which to rely. The undersigned needed an expert report to clear up these discrepancies.

The undersigned then reviewed in detail the facts of this case. Petitioner received Tdap in his right arm on September 14, 2011. Med. recs. Ex. 1, at 1. On September 16, 2011, just two days later, petitioner saw Dr. David Madder at Johns Hopkins for his annual examination. One would think that if petitioner's right arm hurt at the vaccine site, he would have mentioned it to Dr. Madder. Petitioner's history was recurrent left shoulder dislocation, but he said nothing about his right shoulder. Med. recs. Ex. 3, at 13, 15, 16.

On December 5, 2012, which is one year and almost three months after petitioner received Tdap vaccine, petitioner saw Dr. Stewart Koehler, an orthopedist, complaining about shoulder pain whose onset had been gradual and had been occurring in a persistent pattern for one year. Med. recs. Ex. 4, at 3. An MRI performed on petitioner's right shoulder on December 11, 2012 showed a rotator cuff tear. Id.

One year and five months after the vaccination, on February 12, 2013, petitioner changed his history. He told Dr. Allan Genut, a neurologist, that he developed a deep, sharp ache in his upper right deltoid after receiving Tdap vaccine in September 2011. He said the ache waxed and waned for a year but had now dissipated. About three months later, he said to Dr. Genu, he developed a burning sensation on the anterior aspect of the right shoulder and right periocordium which periodically radiated down the upper arm, forearm, and occasionally into the thumb and index finger and the little finger. Within the last two months, he said he had similar burning pain although less intense on the anterior aspect of the left shoulder and precordium. Med. recs. Ex. 7, at 4. Dr. Genut did a physical examination of petitioner and concluded petitioner had full range of motion of his right shoulder. Dr. Genut wrote, "I am unable to find any neurological abnormality to explain the patient's symptoms." Id.

Continuing the history in the August 7, 2017 Order, the undersigned noted that petitioner's history to Dr. Tae Hwan Chung on July 15, 2016 remarkably diverged from his initial history to Dr. Madder, his personal care physician, whom petitioner saw two days (or 48 hours) after Tdap vaccination. Petitioner told Dr. Chung that he had aching around the vaccine site one day after the vaccination and the pain worsened until his shoulder froze. Med. recs. Ex. 17, at 1. Petitioner's claim that his shoulder froze conflicts with Dr. Genut's examination of petitioner's right shoulder on February 12, 2013 in which petitioner's right shoulder was perfectly normal. If indeed petitioner now has macrophagic myofasciitis and rotator cuff tendinopathy, it does not mean, in light of petitioner's earlier medical records including histories and physical exams, that Tdap vaccine caused them. Dr. Chung noted it was unlikely that petitioner had brachial neuritis because he did not have sensory symptoms. Id. at 5. At Dr. Chung's request, petitioner had an EMG and a nerve conduction test done on August 23, 2016, which was normal. Med. recs. Ex. 19, at 1. Petitioner also had an MRI done on his right upper extremity on November 11, 2016, which showed mild atrophy and fatty infiltration of the right deltoid muscle, suggesting mild fasciitis. Petitioner had possible low-grade tears of his rotator cuff. Med. recs. Ex. 20, at 1.

When petitioner saw Dr. Chung again on January 12, 2017, Dr. Chung stated petitioner's pain came mainly from his rotator cuff. Med. recs. Ex. 21, at 12. Dr. Chung also wrote that petitioner was allergic to diphtheria toxin preparations, pertussis vaccines, and tetanus vaccines and toxoid. However, he based this statement on the history petitioner gave him, which was in direct conflict with the earlier medical records which Dr. Chung never saw. Id. Considering that petitioner's right deltoid had only mild fasciitis, Dr. Chung did not pursue a diagnosis of macrophagic myofasciitis, although he was concerned that petitioner might eventually have it since petitioner told Dr. Chung that his injury followed the vaccination. Id. Dr. Chung suggested petitioner have a muscle biopsy in future to confirm Dr. Chung's suspicion of

macrophagic myofasciitis which might be due to petitioner's poor digestion of vaccine-related aluminum compound by macrophages. <u>Id.</u> During Dr. Chung's physical examination of petitioner, he did not record that petitioner had a frozen shoulder.

Further in the Order of August 7, 2017, the undersigned answered petitioner's question why the undersigned does not consider his medical records clearly supportive of his allegations. The undersigned answered in the Order of August 7, 2017 that the later medical records (including Dr. Chung's records) do not support petitioner's factual statements earlier in the medical records which do not validate he had any shoulder pain within 48 hours of the vaccination. Petitioner also asked where he could find experts to comment on his case and whether he could file a letter from Dr. Chung. The undersigned responded that if petitioner seeks an expert medical opinion either from Dr. Chung or someone else, he has to provide the doctor with all of his medical records, not just give him a history (that varies from his earlier histories) and expect the doctor's opinion to be credible. The undersigned stated that the undersigned will not accept the opinion of a doctor who has not read all the exhibits petitioner filed in this case. If Dr. Chung refuses to participate, the undersigned suggested petitioner contact any neurologist or orthopedist to seek an expert report. The undersigned repeated the deadline the undersigned set in the August 1, 2017 Order that petitioner shall file an expert report by September 29, 2017.

Petitioner never filed a response to respondent's amended Rule 4(c) Report or a sur-reply to respondent's response to the undersigned's Order to Show Cause by the deadline of September 5, 2017 or at any time thereafter.

On September 8, 2017, the undersigned issued another Order stating that petitioner has waived his response by not filing one. For a third time, the undersigned stated the deadline for petitioner to file an expert report was September 29, 2017. The undersigned stated that if petitioner did not file an expert report by that date, the undersigned will dismiss petitioner's case for failure to prosecute.

Petitioner never filed an expert report by the deadline September 29, 2017 or thereafter. The undersigned **DISMISSES** petitioner's case for failure to prosecute, failure to comply with the undersigned's orders, and failure to make a prima facie case of causation in fact.

FACTS

Pre-vaccination records

On August 23, 2011, petitioner saw Dr. LoAn N. Lai at Patient First. Med. recs. Ex. 2, at 2. Petitioner had an upper respiratory infection and complained of pain in his left elbow for two weeks. He had been doing a lot of twisting and lifting things in abnormal positions. Dr. Lai diagnosed petitioner with tendinitis. <u>Id.</u>

Post-vaccination records

On September 14, 2011, petitioner received Tdap vaccine in his right arm. Med. recs. Ex. 1, at 1.

On September 16, 2011, just two days after the vaccination, petitioner saw his personal care physician Dr. David Madder at Johns Hopkins for his annual physical examination. Med. recs. Ex. 3, at 13. Petitioner's past medical history was recurrent left shoulder dislocation, as well as chronic sinusitis, headache, being overweight, chest pain, hyperglycemia, hyperlipidemia, anxiety disorder, and depression. Id. Petitioner complained of joint pain, muscle cramps, and stiffness. Id. at 15. He mentioned nothing in particular about his right shoulder. Dr. Madder performed a physical examination and did not note anything abnormal. Id. at 16. For petitioner's recurrent left shoulder dislocation, Dr. Madder noted petitioner was better and he was careful. Id. at 17.

On December 5, 2012, almost 15 months after Tdap vaccination, petitioner saw Dr. Stewart Koehler, an orthopedist. Med. recs. Ex. 4, at 3. Petitioner complained about right shoulder pain whose onset had been gradual and been occurring in a persistent pattern for one year. The pain was moderate, but worsening over time. The pain was a dull ache and burning. Petitioner's work duties, such as overhead activity and lifting, aggravated the shoulder pain. He had painful and decreased range of movement, a burning sensation, difficulty with overhead activities, difficult dressing himself, and difficulty with pushing, pulling, and lifting. He has not seen anyone but Patient First. He did not have previous physical therapy or surgery. He did not use assistive devices and had not been on previous medication. Id. Dr. Koehler did a physical examination after which he noted joint and muscle pain, and muscle weakness. Id. at 4. Petitioner complained of headaches and numbness. Dr. Koehler ordered an MRI. Id.

On December 11, 2012, petitioner had an MRI of his right shoulder because of pain, and ruling out a rotator cuff tear. <u>Id.</u> at 2. The results were slight changes of tendinosis in the supraspinatus tendon. There was no evidence of a rotator cuff tear. Petitioner's acromioclavicular joint was unremarkable. He did not have significant subdeltoid or subacromial fluid. He had slight degenerative subchondral marrow changes in the humeral head. He had changes of tendinosis in the distal subscapularis tendon. There was no evidence of a complete tear. He had thinning of the proximal portion of the long head of the biceps tendon at the level of the proximal aspect of the bicipital groove consistent with a partial tear. A small amount of fluid surrounded the tendon. There was no definite labral tear. The articular cartilage of the osseous glenoid was intact. The bone marrow signal was unremarkable. His muscles were intact. Dr. Robert Van Besten concluded that petitioner did not have a rotator cuff tear. He had tendinosis in the supraspinatus tendon. Because of a slight increase in fluid surrounding the long head of the biceps tendon, he may have associated tenosynovitis. <u>Id.</u>

On February 12, 2013, 17 months after Tdap vaccination, petitioner saw Dr. Allan Genut, a neurologist. Med. recs. Ex. 6, at 3. His history changed from the one he gave to Dr. Koehler two months earlier. Petitioner said that after a DPT vaccine in September 2011, he developed a deep, sharp ache in his upper right deltoid which waxed and waned, but persisted for a year, and

was now dissipated. About three months later, he developed a burning sensation on the anterior aspect of the right shoulder and the right pericardium which periodically radiated down his upper arm, forearm, and occasionally into his thumb, index finger, and little finger. Most of the distal radiation had subsided, but he still had burning pain in the shoulder and upper arm. <u>Id.</u> Within the last two months, he had a similar burning pain although less intense on the anterior aspect of his left shoulder and precordium. He and his wife noticed atrophy at the right shoulder girdle. <u>Id.</u> at 4. Dr. Genut did a physical examination of petitioner and noted petitioner had full range of motion of his right shoulder. Dr. Genut's impression was, "I am unable to find any neurological abnormality to explain the patient's symptoms." <u>Id.</u> He said that petitioner's burning sensation radiating all the way down to his hand did not suggest shoulder pathology. <u>Id.</u>

On February 20, 2013, 17 months after Tdap vaccination, petitioner saw Dr. Bruce Rabin, a neurologist, for a nerve conduction study and an EMG. <u>Id.</u> at 1. His conclusion was that had a right median neuropathy at the wrist affecting the sensory fibers only, but no evidence of distal axonal degeneration and no evidence of radiculopathy or plexopathy. <u>Id.</u>

The undersigned has discussed more recent medical records and more changes in onset history (within a couple of weeks to Dr. Ratain; within 48 hours to Dr. Chung) earlier in this opinion.

DISCUSSION

To satisfy his burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" <u>i.e.</u>, "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." <u>Grant</u>, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. <u>Id.</u> at 1148.

Petitioner must show not only that but for his Tdap vaccination, he would not have tendinosis, but also that Tdap vaccine was a substantial factor in causing his tendinosis. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Petitioner's medical records do not

support that he has SIRVA. He never filed an expert report that he had SIRVA.

Under the Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), the undersigned may not rule in petitioner's favor based solely on his allegations unsupported by medical records or medical opinion. Petitioner repeatedly insisted that he did not need an expert report because he has SIRVA, but petitioner cannot diagnose himself. Respondent denies petitioner had SIRVA.

Petitioner repeatedly made the assumption that the undersigned can diagnose his alleged arm injury as SIRVA. However, the Federal Circuit forbids special masters from diagnosing injuries. In Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994), the Federal Circuit states, "The special masters are not 'diagnosing' vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [vaccinee's] injury, or that the [vaccinee's] injury is a table injury" The Federal Circuit's decisions are binding on the undersigned. Guillory v. Sec'y of HHS, 59 Fed. Cl. 121, 124 (2003), aff'd, 104 F. App'x 712 (Fed. Cir. 2004).

In order for the undersigned to agree that petitioner has SIRVA, his treating medical doctors would need to substantiate that he has SIRVA in their records, which they have not done, or he needed to file a medical expert report substantiating that he has SIRVA, which petitioner has not done.

Moreover, the undersigned has a serious problem with petitioner changing his medical history from the one he gave Dr. Madder two days after vaccination to the ones he gave after a year post-vaccination. What is most significant for the purpose of petitioner's assertion in his amended petition that he has the Table injury of SIRVA is that when he saw his personal care physician Dr. Madder two days (which is 48 hours) after his Tdap vaccination, he did not complain of any problem, i.e., pain, burning, in his right shoulder. That means he does not qualify for the Table injury of SIRVA for which causation is presumed since that Table injury requires onset within 48 hours of the vaccination. That leaves him the only option to prove causation in fact and he never filed an expert report although the undersigned gave petitioner ample opportunity to do so and warned him in repeated orders of the consequences of failing to do so.

From reporting nothing in particular about his right arm to giving a history over a year later that he had gradual worsening of aching in his arm, petitioner has varied in his histories. Sometimes petitioner told medical providers that onset was within 48 hours. Other times, he said onset was in a few days. Still at other times, he said onset was in a few weeks.

Having a conflict among the histories a petitioner gave in contemporaneous medical records and the histories he gave later has occurred often in the Vaccine Program. The Federal Circuit has advised that the best practice is to find credible the earliest history since it is closer in time to the vaccination and any sequelae thereof. Well-established case law holds that information in contemporary medical records is more believable than that produced years later at

trial. <u>United States v. United States Gypsum Co.</u>, 333 U.S. 364, 396 (1948); <u>Burns v. Secretary</u>, <u>HHS</u>, 3 F.3d 415 (Fed. Cir. 1993); <u>Ware v. Secretary</u>, <u>HHS</u>, 28 Fed. Cl. 716, 719 (1993); <u>Estate of Arrowood v. Secretary</u>, <u>HHS</u>, 28 Fed. Cl. 453 (1993); <u>Murphy v. Secretary</u>, <u>HHS</u>, 23 Cl. Ct. 726, 733 (1991), <u>aff'd</u>, 968 F.2d 1226 (Fed. Cir.), <u>cert. denied sub nom. Murphy v. Sullivan</u>, 113 S. Ct. 263 (1992); <u>Montgomery Coca-Cola Bottling Co. v. United States</u>, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

The undersigned therefore takes the history that petitioner gave to Dr. Madder two days after the vaccination, during which he never complained of a right shoulder problem, as more credible of his not having SIRVA, than his later histories which vary from this earliest history. Petitioner always had the alternative to prove causation in fact. The undersigned gave petitioner two months to file an expert report. Petitioner never filed an expert report.

The undersigned **DISMISSES** this petition under Vaccine Rule 21(b)(1) for failure to prosecute and failure to comply with the undersigned's orders. In addition, the undersigned also dismisses this petition for petitioner's failure to make a prima facie case of causation in fact.

CONCLUSION

The petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.²

IT IS SO ORDERED.

Dated: October 11, 2017

Laura D. Millman Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.